

DSJ1&2-PR Exh 535

From: Joseph Tomkiewicz
To: Colleen McGinn
Sent: 10/28/2015 8:16:13 PM
Subject: RE: Publix Anda weekly call

Colleen,

Based on previous investigations, I think it is highly likely that at a corporate level, Publix is not aware of these issues. We should schedule a face-to-face meeting with the relevant Publix stakeholders to discuss their ongoing prescriber due diligence and related diversion control efforts.

Because this primarily involves another company's (Alvogen) product, I am comfortable releasing the product we currently have on hold, provided Publix agrees not to distribute our oxycodone products to these nine locations (0202, 0410, 0419, 0527, 0537, 0738, 1201, 1287, and 1477) until they've conducted a review of diversion control efforts at these nine locations, and addressed our below concerns.

Thanks,

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OUR PURPOSE & VALUES

From: Joseph Tomkiewicz
Sent: Wednesday, October 28, 2015 3:39 PM
To: Colleen McGinn
Subject: RE: Publix Anda weekly call



Colleen,

On October 27, 2015, I received data concerning oxycodone usage at Publix Super Market, Inc. The data comprised of total dosage units dispensed of all oxycodone tablet SKUs for the month of September 2015 for their top ten locations, along with a list of the top five oxycodone prescribers for each location. The following is an analysis of the data received.

There were ten locations listed (0202, 0410, 0419, 0527, 0537, 0738, 1201, 1287, 1477, and 3210). All stores are located in the State of Florida. Location 3210 is located on the campus of Moffitt Cancer Center; all 3210-listed physicians are associated with MCC; oxycodone products and quantities at 3210 appear to be consistent with a large oncology practice. The balance of the retail locations are typical retail, located inside grocery stores.

Oxycodone IR 30mg data was examined due to its status as a highly sought-after product among abusers, and due to its limited use in retail pharmacy (based on AmerisourceBergen sales data for the six months ending June 2012: the average DEA registrant who purchased oxycodone purchased an average of 4.461 tablets of all oxycodone SKUs, of which 695 tablets were oxycodone IR 30mg. The median was 1.817 tablets of all oxycodone, and **no oxycodone IR 30mg** the average percentage that oxycodone IR 30mg comprised all oxycodone purchases among all registrants who purchased oxycodone was 9.5%). The following quantities and percentages of oxycodone IR 30mg were noted for the nine retail locations:

| Location | All Oxycodone | IR 30mg | % IR 30mg |
|----------|---------------|---------|-----------|
| 0202 | 10,670 | 4,894 | 45.9% |

| | | | |
|------|--------|-------|-------|
| 0410 | 10,083 | 4,600 | 45.6% |
| 0419 | 7,648 | 3,735 | 48.8% |
| 0527 | 8,857 | 3,348 | 37.8% |
| 0537 | 10,554 | 2,683 | 25.4% |
| 0738 | 7,656 | 2,886 | 37.7% |
| 1201 | 8,535 | 2,985 | 35.0% |
| 1287 | 13,683 | 8,023 | 58.6% |
| 1477 | 7,322 | 2,680 | 36.6% |

At each location with the exception of 0537, oxycodone IR 30mg, the highest strength immediate release oxycodone available, was the top oxycodone product dispensed. By contrast, at the Moffitt Cancer Center, the top oxycodone product dispensed was IR 5mg (42.3%), the lowest strength non-combination product available.

Inquiries into the top prescribers at each location uncovered the following information:

For Melbourne, FL location 202—

- Dr. Ralph Page

Anecdotally appears to be a cash-only pain clinic business (\$140 up-front fee), but he holds no pain clinic license.

- Dr. Mahmoud El-Tobgui

He is an OB/GYN who is currently operating pain clinic

Anecdotal evidence suggests that the pain clinic is cash-only (\$200 up-front fee for first visit, \$170 up-front subsequent visits).

- Dr. Thomas Vellef

He was disciplined for abandoning a previous practice.

According to the Treasure Coast Palm, Vellef had a previous practice that had "carloads" of out-of-state patients.

His prior landlord refused to renew office space lease due to the appearance of running a pill mill.

There is significant anecdotal evidence of pill mill activity with his current practice.

For Melbourne, FL location 738—

- Dr. Mahmoud El-Tobgui (see above)
- Dr. Thomas Vellef (see above)
- Dr. Scott Hardoon

Practice is a family-run (father and brother) clinic whose pain clinic license was revoked by the state.

There is anecdotal evidence of a \$600 cash fee to enroll as a pain patient

There is significant anecdotal evidence that former pain patients belonging to Dr. John Gayden (whose license was relinquished due to over prescribing controlled substances and trading prescriptions for sex with underage patients) are now patients at his clinic.

For Naples, FL location 410—

- Dr. Kevin Sheahan

His pain clinic practice is located in Atlanta, GA, which is 628 Miles from this store.

He relinquished his FL license in 1998.

For North Port, FL location 1287—

- Dr. Michael Mozzetti

He runs an Urgent Care Clinic that anecdotally doesn't take urgent care or emergency patients.

There is significant anecdotal evidence of pill mill activity

- Dr. James Porcelli

According to media reports, he abandoned his previous practice in Naples earlier this year without informing his patients or paying his staff

For Ocala, FL location 1477—

- Dr. Naglaa Abdel-Al

Her practice is either 78.3 miles (according to the DEA) or 40.8 miles (according to Florida license) from the store.

She was disciplined in Arizona for abandoning an anesthetized patient in order to inject/abuse a sedative, resulting in her overdose.

For Ocala, FL location 0419—

- Dr. Qing McGaha

Her office appears to be 116 miles from the store.

Let me know your thoughts.

Thanks,



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OUR PURPOSE & VALUES

From: Joseph Tomkiewicz
Sent: Tuesday, October 27, 2015 3:35 PM
To: Jocelyn Baker
Cc: Christine Baeder; Michelle Osmian; Jennifer King; Kevin Galownia; Colleen McGinn
Subject: RE: Publix Anda weekly call

Jocelyn,

Thanks for getting this data. This will take me at least a day to go through. I will say that at first glance, there will be some additional questions into their anti-diversion efforts, and once we've researched the doctors, there may be more questions.

Thanks,



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OUR PURPOSE & VALUES

From: Jocelyn Baker
Sent: Tuesday, October 27, 2015 3:20 PM
To: Christine Baeder; Michelle Osmian; Joseph Tomkiewicz; Jennifer King; Kevin Galownia
Subject: FW: Publix Anda weekly call
Importance: High

Per your request... Publix data.
Please advise of next steps or when the customer order will be released.
Thanks-



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From: Gary Blessin (External) [<mailto:Gary.Blessin@publix.com>]
Sent: Tuesday, October 27, 2015 3:13 PM
To: Jocelyn Baker
Subject: FW: Publix Anda weekly call

Here you go. Finally got all the data.

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From: Erin Avella
Sent: Tuesday, October 27, 2015 3:04 PM
To: Gary Blessin
Cc: Chris Hewell; Melissa Rittenhouse
Subject: RE: Publix Anda weekly call

Gary,
As requested, here is the Oxycodone data (9/1-9/30/2015):

(Tab 1) Stores - A list of their top 10 stores by oxycodone tablet volume;
(Tab 2) Volume - A breakdown by SKU of their oxycodone ER and IR volume at each of the 10 stores;
(Tab 3) Prescribers - A list of the top 5 prescribers, including DEA number, at each of the 10 locations

Thank you.

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